



PATENTS  
CUSTOMER NO. 29052  
ATTY. DOCKET NO. 23578-0009

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Zatezalo et al.	)	
	)	Art Unit: To Be Assigned
Serial No.: 10/698,047	)	
	)	Examiner: To Be Assigned
Filed: October 30, 2003	)	
	)	
For: Fluid Injection System Providing	)	
Visual Stimuli	)	

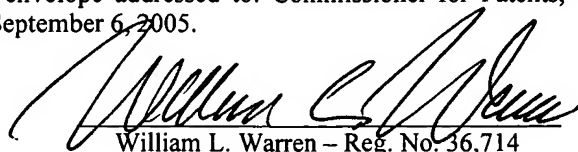
**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.56  
AND NOTICE OF RELATED LITIGATION UNDER 37 CFR 1.178**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement and Notice of Related Litigation are filed in accordance with 37 CFR §1.56, §1.97, §1.98 and §1.178. Applicants herewith disclose references and call to the attention of the Examiner the pending federal court litigations relating to U.S. Patent No. 6,339,718 ("the '718 patent") and U.S. Patent No. 6,643,537 ("the '537 patent"), the patents to which this application claims priority, that may be deemed to be relevant to the patentability of the above-identified application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 6, 2005.

  
William L. Warren – Reg. No. 36,714

In re Application of: Zatezalo et al.  
Serial No.: 10/698,047  
Filing Date: October 30, 2003  
IDS & Notice of Litigation

Applicants respectfully submit that the references and any litigation related documents and/or materials are made of record to assist the Examiner in the examination of the above-identified application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teachings and relevance to this application.

#### I. References Cited in Corresponding Applications

The references listed on the attached Form PTO-1449 have been disclosed and/or made of record in the prosecution of the '718 patent and its related patents/applications, including U.S. Patent No. 6,643,537 ("the '537 patent"), a continuation-in-part of the '718 patent; U.S. Application Serial No. 09/941,224 ("the '224 application"), a continuation application of the '718 patent, U.S. Application Serial No. 10/309,413 ("the 413 application"), a continuation-in-part of the '537 patent, and a Reissue Application Serial No. 10/757,348 ("the '348 reissue application"). Copies thereof may be found in the corresponding application files.

The citations of these references do not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicants may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

#### II. Notice of Pending Litigations Related to the '718 and the '537 patents: MPEP 2001.06 (c)

1. *Medrad, Inc. v. Tyco Healthcare Group, LP, et al.*, Civil Case No. 01-1997-DEC, U.S.D.C. (W.D. Penn.) ("the Pennsylvania litigation")

Applicants had notified the Patent Office about this Pennsylvania litigation related to the '718 patent during the prosecutions of the '537 patent, the '224 application, the '413 application and the '348 reissue application. The litigation documents exchanged by Medrad and Tyco and Nemoto in this Pennsylvania litigation were provided to the Examiner during the prosecutions of these patent applications. Therefore, copies thereof may be found in the corresponding application files, if the Examiner desires.

2. *Tyco Healthcare Group LP, et al. v. Medrad, Inc.*, Civil Case No. 04-773, U.S.D.C. (S.D. Ohio) ("the Ohio litigation")

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Applicants hereby notify the Examiner that the '718 patent and the '537 patent" have also been involved in the Ohio litigation instituted by Tyco Healthcare Group LP ("Tyco"), Mallinckrodt Inc. ("Mallinckrodt") and Liebel-Flarsheim Company ("L-F"), against Medrad for Declaratory Judgment. This Ohio litigation was filed in the United States District Court for the Southern District of Ohio on November 15, 2004, under Civil Case No. 04-773.

In the Ohio litigation, Tyco et al. alleged that the '718 and the '537 patents are invalid, unenforceable and the claims of the '718 and the '537 patents are not infringed (*See* Tyco et al.'s Complaint of November 15, 2004). The litigation documents cited in the attached Forms 1449 have been disclosed and/or made of record in the related pending Applications: the '224 application, the 413 application and the '348 reissue application, and copies thereof may be found in the corresponding application files.

- 1) Tyco et al.'s Complaint for Declaratory Judgment and Jury Demand dated November 15, 2004;
- 2) Medrad's Answer and Counterclaims filed December 28, 2004;
- 3) Tyco's Reply to Defendant's Counterclaims filed January 20, 2005;
- 4) Tyco's First Set of Interrogatories Nos. 1-8 to Defendant filed February 7, 2005;
- 5) Tyco's First Set of Requests for Production of Documents to Defendant filed February 7, 2005;
- 6) Medrad's Responses and objections to Plaintiffs' First Set of Requests for Production of Documents to Defendant filed March 11, 2005;
- 7) Medrad's Responses to Plaintiffs' First Set of Interrogatories Nos. 1-8 to Defendant filed March 11, 2005;
- 8) Medrad's First Set of Requests for Production of Documents and Things to Plaintiffs filed March 18, 2005;
- 9) Medrad's First Request for Entry Upon Land and Inspection of Things Thereon to Plaintiffs filed March 18, 2005;

10) Medrad's Consent Motion to Amend Answer and Counterclaims filed March 24, 2005;

11) Medrad's Amended Answer and Counterclaims filed March 24, 2005;

12) Medrad's First Set of Interrogatories (Nos. 1-9) filed March 24, 2005;

13) Tyco's Reply to Defendant's Amended Counterclaims filed April 27, 2005;

14) Tyco's Response to Medrad's First Set of Requests for Production of Documents and Things filed May 20, 2005; and

15) Tyco's Response to Medrad's First Set of Interrogatories (Nos. 1-9) filed May 26, 2005.

In Medrad's Answer and Counterclaims to Tyco's Complaint, and later, in Medrad's Amended Answer and Counterclaims to Tyco's Complaint, Medrad modified the "Facts" section of its Counterclaims by referring to U.S. Patent No. 6,743,205 ("the '205 patent), adding a Third Counterclaims alleging infringement of the '205 patent, and modifying Medrad's Prayer for Relief. Validity and infringement allegations relating to the '718 and the '537 patents are also set forth in the Amended Answer and the First and Second Counterclaims. However, in Tyco's Reply to Medrad's Counterclaims and Amended Counterclaims, Tyco et al. denied the infringement allegations of Medrad's Counterclaims relating to the '718 patent and the '537 patent, respectively.

In Medrad's Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-8), Medrad objected that the interrogatory was premature in that limited discovery has been done. Medrad further asserted that Medrad's investigation of infringement by Tyco et al. is ongoing but alleged that Plaintiffs' OptiVantage™ DH injection system literally infringes at least claims 24 and 27 in the '718 patent (pages 7-8) and claims 6, 19 and 22 in the '537 patent (pages 4-7). In Medrad's Responses and Objections to Plaintiffs' First Set of Requests for Production of Documents and Things, Medrad objected to each request as being duplicative, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence (General Objections on page 1; and Responses to each Request).

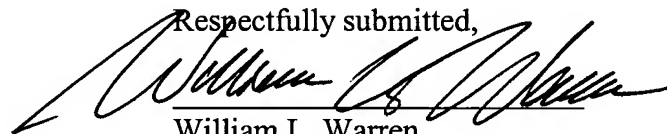
In Tyco's Responses to Medrad's First Set of Requests for Production of Documents and Things, Tyco simply objected each Request to the extent that 1) each Request sought the production of documents or things that are protected by the attorney-client and/or work product privileges; 2) the Requests sought information unrelated to any claim or defense in this action and is likely to lead to the discovery of admissible evidence; and/or 3) the Requests were overly broad and burdensome. In Plaintiffs' Responses to Medrad's First Set of Interrogatories (Nos. 1-9), non-infringement allegations relating to the '718 patent and the '537 patent are set forth on page 6 (Response to Interrogatory No. 5) with references to the preliminary non-infringement chart attached as Exhibit A. Unpatentability and invalidity allegations, and unenforceability due to inequitable conduct allegations relating to the '718 patent and the '537 patent are set forth on pages 6-8 (Response to Interrogatory No. 6); pages 8-9 (Response to Interrogatory No. 7); and pages 9-21 (Response to Interrogatory No. 8). Note that information relating to the '718 patent and the '537 patent of alleged prior art, Nemoto Sonic Shot 50 MR injector, the Medrad MR Spectris Injector, the Injektron 82 MRT 1.4 manual, U.S. Patent No. 5,472,403 to Cornacchia, and U.S. Patent No. 5,806,519 to Evans, III were disclosed in numerous documents submitted with the Information Disclosure Statement, and were also considered by the Patent Office during the prosecutions of the '718 patent and the '537 patent, respective (*See, for example*, IDS submitted on November 1, 2000; First Office Action dated December 18, 2000; and IDS submitted on May 17, 2001 during the prosecution of the '718 patent; *see also, for example*, IDS and Notice of Related Litigation submitted on May 19, 2003, and IDS submitted on May 29, 2003 during the prosecution of the '537 patent).

Applicants believe that certain of the alleged prior art references are not or may not be prior art to the application, and therefore reserve the right to assert that one or more of the references is not prior art to this application. Moreover, Applicants believe they can successfully swear behind many, if not all, of the Section 102 (a) and (e) references based on prior conception and/or reduction to practice.

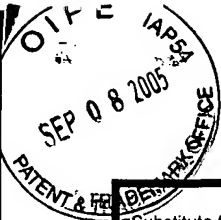
Nevertheless, Applicants would like the Examiner to at least initially consider the subject matter disclosed in the relevant references vis-à-vis the pending claims because Applicants believe the claims will define over the references.

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The Examiner is encouraged to call the undersigned attorney at 404-853-8081 if doing so will facilitate prosecution of the application. No fees are believed to be due at this time. However, the commissioner is hereby authorized to charge any additional fees due or credit any overpayment to Deposit Account 19-5029 (Ref. 23578-0009).

Respectfully submitted,  
  
William L. Warren  
Reg. No. 36,714

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999 Peachtree Street, NE  
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Attorney Docket No.: 23578-0009



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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/698,047
				Filing Date	October 30, 2003
				First Named Inventor	Zatezalo et al.
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	4	Attorney Docket Number	23578.0009

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	US-3,888,239	06/10/75	Rubinstein	
	A2	US-4,006,736	02/08/77	Kranys, et al.	
	A3	US-4,553,958	11/19/85	LeCocq	
	A4	US-4,677,980	07/07/87	Reilly, et al.	
	A5	US-4,710,166	12/01/87	Thompson, et al.	
	A6	US-5,304,126	04/19/94	Epstein, et al.	
	A7	US-5,383,858	01/24/95	Reilly, et al.	
	A8	US-5,472,403	12/05/95	Cornacchia, et al.	
	A9	US-5,494,036	02/27/96	Uber III, et al.	
	A10	US-5,553,619	09/1996	Prince	
	A11	US-5,573,515	11/1996	Wilson	
	A12	US-5,779,649	09/01/98	Prince	
	A13	US-5,782,805	07/21/98	Meinzer, et al.	
	A14	US-5,806,519	09/15/98	Evans III, et al.	
	A15	US-6,442,418	08/27/02	Evan III, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Patent Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>2</sup> (if known)				
	B1	Europe 0 192 786	09/03/86			
	B2	Europe 0 302 752	02/08/89			
	B3	WIPO 01/08730	02/08/01			

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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NON PATENT LITERATURE DOCUMENTS				
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	C1	International Search Report for Counterpart PCT Application No. PCT/US00/20770		
	C2	MCT/MCT Plus Operation Manual, pages 5-1 to 5-9 and 7-1 to 7-15, (1991); KMP 810P, Rev. B		
	C3	Medrad Spectris MR Injector Operation Manual; pages 2-1 to 2-18, 4-1 to 4-8 and 6-1 to 6-10 (1996); 92901-T-107, Rev. E.		
	C4	Medrad Envision CT Injector Operation Manual; pages 2-1 to 2-36 and 4-1 to 4-13 (1995); 92401-T-123, Rev. E.		
	C5	Medrad Vistron CT Injection System Operation Manual; pages 21-26 (2000); 95403-T-141, Rev. B.		
	C6	Optistar MR Injector System 510(k) Summary (11/4/1998).		
	C7	Optistar MR Contrast Delivery System Brochure (2000).		
	C8	Optistar MR Digital Injection System Operator's Manual, 801900-A (November 1999).		
	C9	MR Sonic Shot 50 Operator's Manual (with Accompanying English Translation of Chapter 11), Ver. 2.0.0 (December 24, 1999).		
	C10	Injektron 82 MRT User Instructions, Version MR2 (March 10, 1999).		
	C11	Injektron 82 MRT User Instructions, Version MR 1.4 (October 1997).		
	C12	English Translation of Injektron 82 MRT User Instructions, Version MR 1.4 (October 1997).		
	C13	Injektron 82 MRT Operating Instructions, MR 1.4 Version (October 1997).		
	C14	English Translation of Injektron 82 MRT Operating Instructions, MR 1.4 Version (October 1997).		
	C15	E-Z-EM, Inc.; PercuPump II Touch*Screen CT Injector System; Manual and Operations Guide; 1996		
	C16	Liebel-Flarsheim Company CT 9000 Digital Injection System Operator's Manual; 800850 Rev F; Nov. 1995		

Examiner Signature		Date Considered	
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Sheet	3	of	4	

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	C17	<i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> , Civil Case No. 04-773, U.S.D.C. (S.D. Ohio):	
	C18	Tyco's <u>Complaint for Declaratory Judgment and Jury Demand</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (November 15, 2004)	
	C19	Medrad's <u>Answer and Counterclaims</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (December 28, 2004).	
	C20	Tyco's <u>Plaintiffs' Reply to Defendant's Counterclaims</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (January 20, 2005).	
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	C23	Medrad's <u>Responses and Objections to Plaintiffs' First Set of Requests for Production of Documents</u> to Defendant, Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 11, 2005).	
	C24	Medrad's <u>Response to Plaintiffs' First Set of Interrogatories (Nos. 1-8) to Defendant</u> , Civil Action No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 11, 2005).	
	C25	Medrad's <u>First Set of Requests for Production of Documents and Things</u> to Plaintiffs, Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 18, 2005).	
	C26	Medrad's <u>First Request for Entry Upon Land and Inspection of Things Thereon</u> to Plaintiffs, Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 18, 2005).	
	C27	Medrad's <u>Consent Motion to Amend Answer and Counterclaims</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 24, 2005).	
	C28	Medrad's <u>Amended Answer and Counterclaims</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 24, 2005).	
	C29	Medrad's <u>First Set of Interrogatories (Nos. 1-9)</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (March 24, 2005).	
	C30	Tyco's <u>Reply to Defendant's Amended Counterclaims</u> , Civil Case No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (April 27, 2005).	
	C31	Tyco's <u>Response to Medrad's First Set of Requests for Production of Documents and Things</u> , Civil Action No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (May 20, 2005).	
	C32	Tyco's <u>Response to Medrad's First Set of Interrogatories (Nos. 1-9)</u> , Civil Action No. 04-773, <i>Tyco Healthcare Group LP et al. v. Medrad, Inc.</i> (May 26, 2005).	

Examiner Signature		Date Considered	
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	C33	<u>Medrad, Inc. v. Tyco Healthcare Group, LP et al.</u> , Civil Case No. 01-1997-DEZ, U.S.D.C. (W.D. Penn.).		
	C34	Medrad's Amended Complaint, Civil Action No. 01-1997-DEZ, Medrad, Inc. v. Tyco Healthcare Group LP, et al. (January 15, 2002)		
	C35	Tyco's Answer and Counterclaim to Amended Complaint, Civil Action No. 01-1997-DEZ, Medrad, Inc. v. Tyco Healthcare Group LP, et al. (January 28, 2002).		
	C36	Tyco's Response to Medrad's First Set of Interrogatories (Nos. 1-5), Civil Action No. 01-1997-DEZ, Medrad, Inc. v. Tyco Healthcare Group LP, et al. (March 18, 2002).		
	C37	Tyco's Supplemental Response to Medrad's First Set of Interrogatories (Nos. 1-5), Civil Action No. 01-1997-DEZ, Medrad, Inc. v. Tyco Healthcare Group LP, et al. (April 25, 2002).		
	C38	Tyco's Response to Medrad's Fourth Request for Production of Documents and Things, Civil Action No. 01-1997-DEZ, Medrad, Inc. v. Tyco Healthcare Group LP, et al. (June 24, 2002).		
	C39	Medrad's <u>Second Amended Complaint</u> , Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (March 26, 2002).		
	C40	Tyco's <u>Answer and Counterclaim to Second Amended Complaint</u> , Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (July 8, 2002).		
	C41	Medrad's <u>Answer to Defendants' Counterclaim</u> , Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (July 31, 2002).		
	C42	Medrad's <u>Amended Answer for Defendants' Counterclaim</u> Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (August 9, 2002).		
	C43	Tyco's <u>Preliminary Prior Art and Invalidity Chart as Applied to Claims of U.S. Patent No. 6,339,718 in Response to Interrogatory Nos. 2 and 3</u> (Spectris) (22 pages), Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (undated).		
	C44	Tyco's <u>Prior Art and Invalidity Chart Claims of U.S. Patent No. 6,339,718 in Response to Interrogatory Nos. 2 and 3</u> (Nemoto Sonic Shot) (13 pages), Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (undated).		
	C45	Alleged Nemoto Operators' Manual (labeled MAL-P17-004295 to MAL-P17-004315).		
	C46	Tyco's <u>Preliminary Noninfringement Chart of U.S. Patent No. 6,339,718 in Response to Interrogatory No. 7</u> , Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (undated).		
	C47	Nemoto's Responses to Medrad's First Requests for Admissions (Nos. 1-25), Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (December 2, 2002).		
	C48	Tyco's Responses to Medrad's First Set of Requests for Admissions Nos. 1-37, Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (January 13, 2003).		
	C49	Tyco's <u>Second Supplemental Response to Medrad's First Set of Interrogatories (Nos. 1-5)</u> , Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (January 15, 2003).		
	C50	Photograph of Nemoto's Sonic Shot 50 MR Injector (labeled NEMOTO-012162) (undated).		
	C51	Alleged Nemoto Instruction Manual for Sonic Shot 50 MR Injector (labeled NEMOTO-012137 to 012161) (undated).		
	C52	Alleged Nemoto Instruction Manual for Sonic Shot 50 MR Injector (labeled NEMOTO-001989 to NEMOTO-0120800) (Japanese and English)		
	C53	<u>Update</u> , Clinical Imagiology, Vol. 4, No. 6 (June 1993) (labeled NEMOTO-012081 to NEMOTO-012089).		
	C54	Tyco's <u>Response to Medrad's Fourth Set of Request for Admissions</u> (Nos. 54-79), Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (March 31, 2003).		
	C55	Covenant, Civil Action No. 01-1997-DEZ, <u>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</u> (August 11, 2003).		

Examiner Signature	Date Considered
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